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| 08/952,741      | 11/25/1997  | YUJI HATADA          | 2173-106P           | 3031             |

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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT PAPER NUMBER

1652

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/952,741

Applicant(s)

HATADA ET AL.

Examiner

Elizabeth Slobodyansky, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-27 and 29-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date herewith
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed November 12, 2004 canceling claims 28 and 34-43 and amending claims 25, 26, 30, 32 and 33 has been entered.

Claims 25-27 and 29-33 are pending.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Both claim 32 and claim 33 depend from claim 25. Claims 32 and 33 have been amended to encompass a DNA comprising SEQ ID NO:5. Applicant does not indicate and the examiner is unable to locate adequate support in the specification for such amendment because it appears that a complement of SEQ ID NO:5 does not encode any fragment of SEQ ID NO:2 or a sequence that differs therefrom by a single amino acid. Thus there is no indication that a DNA of claim 25 comprising a complement of SEQ ID NO:5 was within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27 and 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25, with dependent claims 26, 27, 29-33, recites "An isolated DNA molecule encoding a modified protein exhibiting alkaline liquefying  $\alpha$ -amylase activity at a pH optimum of 8-9 and possessing an amino acid sequence which has been obtained by modifying an amino acid sequence described in SEQ ID NO:2 in a manner in which one amino acid is substituted, deleted, or inserted without changing enzymological properties of a protein having the amino acid sequence described in SEQ ID NO:2 and wherein said modified protein hydrolyzes 1,4 - $\alpha$  - glucosidic linkages in starches, amylose, amylopectin, and degradation products thereof and in amylose forms: glucose, maltose, maltotriose, maltotriose, maltopentose and maltohexose and does not hydrolyze pullulan". It is noted that the recited properties of "exhibiting alkaline liquefying  $\alpha$ -amylase activity at a pH optimum of 8-9" and "hydrolyzes 1,4 - $\alpha$  - glucosidic linkages in starches, amylose, amylopectin, and degradation products thereof and in amylose forms: glucose, maltose, maltotriose, maltotriose, maltopentose and maltohexose and

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does not hydrolyze pullulan" pertain to a modified protein whereas "enzymological properties" pertain to a protein of SEQ ID NO:2. This renders unclear which enzymological properties of a protein of SEQ ID NO:2 remain unchanged in a modified protein encoded by a DNA of claim 25 other than being an alkaline liquefying  $\alpha$ -amylase having a pH optimum at pH 8-9 and having the recited substrate specificity.

Furthermore, the term "modified protein" may include chemical modification of the amino acid residues, for example, in addition to mutation. Because what is intended to be claimed is a mutation, because the specification provides support for said term at least on page 3, last line, and because there is no explicit support for term "modified protein", the use of "a mutant protein exhibiting ..." is suggested.

Claims 30-33 recite the specific properties of the mutant alkaline liquefying  $\alpha$ -amylase. Properties such as pH optimum recited in the independent claim 25 do not need to be repeated in a dependent claim.

Further, claim 30 recites the ranges of temperature, pH stability, etc. Said ranges depend on conditions such as temperature, substrate, buffer, etc. A temperature range depends on pH, for example. The stability in the presence of cations depends on conditions such as temperature, pH, etc. Furthermore, claim 30 is confusing because the claimed enzyme cannot have a MW of less than 50 kD.

### ***Response to Arguments***

Applicant's arguments filed November 12, 2004 have been fully considered but they are not persuasive.

With regard to the 112, 2<sup>nd</sup> paragraph, rejection, Applicants argue "With respect claims 25-27 and 29-33, Applicants traverse. The Examiner asserts that is unknown what enzymological properties are encompassed by the claims. Claim 25 claims an optimal pH at which the amylase enzyme works as well as functional language directed to what substrate the enzyme will cleave. Applicants do not believe that there is anything vague or indefinite about these enzymological properties as they are recited in the claim. In other words, the "enzymological properties" are defined in the claim" (Remarks, page 7). This is not persuasive because as discussed in the rejection above, the recited properties pertain to a mutant protein while "enzymological properties" are those of a protein of SEQ ID NO:2.

With regard to claim 30, "Applicants assert that because the method determining molecular weight is by polyacrylamide gel electrophoresis, there is some error inherently present the method that would allow one to potentially deduce a molecular weight of less than 50,000 daltons. For example, Applicants note that a molecular weight of a given protein may vary when measured by polyacrylamide gel electrophoresis depending on how spherical the protein is as well as its pI. For these reasons, Applicants submit that there is nothing vague or indefinite about this claim" (page 9). This is not persuasive because polyacrylamide gel electrophoresis is done in SDS (SDS-PAGE) rendering the protein denatured and as result lacking its spherical tertiary structure, if it had it in a native form.

The rejections of claims 28, 34-43 are moot in view of the cancellation of these claims.

**Suggested claims:**

Claim 25. An isolated DNA molecule encoding a mutant protein exhibiting alkaline liquefying  $\alpha$ -amylase activity at a pH optimum of 8-9 and having an amino acid sequence that differs from SEQ ID NO:2 by substitution, deletion, or insertion of one amino acid residue, wherein said mutant protein hydrolyzes 1,4 - $\alpha$  - glucosidic linkages in starch, amylose, amylopectin and does not hydrolyze pullulan.

Or preferably,

Claim 25. An isolated DNA molecule encoding a mutant protein exhibiting alkaline liquefying  $\alpha$ -amylase activity at a pH optimum of 8-9 and having an amino acid sequence that differs from SEQ ID NO:2 by substitution, deletion, or insertion of one amino acid.

Claim 26. An isolated DNA molecule comprising the DNA molecule of claim 25 operably linked to a regulatory nucleotide sequence.

Claim 27. A vector comprising the DNA molecule of claim 26.

Cancel claims 29-33.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

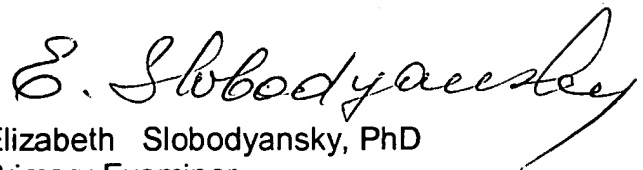
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth Slobodyansky, PhD  
Primary Examiner  
Art Unit 1652

January 18, 2005